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09/627,165	07/27/2000	Jongbae Kim	24170	9845

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

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19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/627,165	Applicant(s) KIM ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-28 and 35-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants claim foreign priority, however, an English translation of the priority document (Republic of Korea 99-30638 filed 7/27/99) has not been submitted. Therefore, the priority date is not perfected.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1, 3, 5, 7, 9, 11, 35 and 37, drawn to a nucleotide sequence encoding a lectin isolated from Korean mistletoe, an isoform of A chain of the lectin, or an isoform of B chain of the lectin, classified in class 536, subclass 23.1.

II. Claims 2, 4, 6, 8, 10, 12-18, 36, 38, 45 and 46, drawn to a lectin isolated from Korean mistletoe, or a lectin peptide involved in biosynthesizing lectin; and a pharmaceutical composition comprising the lectin, classified in class 530, subclass 396, and class 514, subclass 2.

III. Claims 19-22, drawn to a method of preparing a lectin isolated from Korean mistletoe using immuno-affinity column chromatography, classified in class 530, subclasses 396 and 387.1.

IV. Claims 23-28, drawn to a method of enhancing immunity, comprising administering to an animal a lectin isolated from Korean mistletoe, classified in class 530, subclass 396.

V. Claims 29-34, drawn to a method of effectuating antitumor activity, comprising administering to an animal a lectin isolated from Korean mistletoe, classified in class class 530, subclass 396.

VI. Claim 39, drawn to a method of inducing IFN-γ, comprising administering to an animal Korean Mistletoe Heparin Binding Protein (KMHBP), classified in class 530, and subclass 350.

VII. Claims 40 and 47, drawn to a pharmaceutical composition comprising a protein fraction of KMHBP, and a method of preparing the protein fraction of KMHBP, classified in class 530, subclass 350.

VIII. Claim 41, drawn to a method of enhancing immunity, comprising administering to an animal a protein fraction of KMHBP, classified in class 530, subclass 350.

IX. Claims 42, 44 and 48, drawn to a mixture of KML-C and KMHBP, a pharmaceutical composition comprising the mixture of KML-C and KMHBP, and a method of preparing the mixture, classified in class 530, subclasses 350 and 396.

X. Claim 43, drawn to a method of enhancing immunity and effectuating antitumor activity, comprising administering a mixture of KML-C and KMHBP, classified in class 530, subclasses 350 and 396.

Should Invention I be elected, applicant is required to select one nucleotide sequence identified by a "SEQ ID NO:". Each nucleotide sequence, absent factual data to the contrary, is a distinct nucleic acid. This is not species election.

Should Invention II be elected, applicant is required to select one amino acid sequence identified by a "SEQ ID NO:". Each amino acid sequence, absent factual data to the contrary, is a distinct peptide. This is not species election.

3. The inventions are distinct, each from the other because of the following reasons:

The nucleotide of Invention I is related to peptide of Invention II because the peptide can be produced by the expression in the cell. The inventions are distinct because they are physically and functionally distinct chemical entities and the peptide can be made by another process such as solid phase peptide synthesis.

The nucleotide of Invention I is distinct from the products of Inventions VII and Invention IX because they are physically and functionally distinct chemical entities, and the products of Inventions VII and IX cannot be made by the product of Invention I.

The products of Inventions II, VII and IX are distinct from each other because they have different modes of operation and different function, and produce different effects, e.g., Invention II is directed to Korean Mistletoe lectin or lectin peptide, which would have IL-1 induction effect when administering to in animal, while Invention VII is directed to Korean Mistletoe Heparin Binding Protein which would have IFN-γ induction effect, and Invention IX is directed to a mixture of KML-C and KMHBP, which would have the effects of effectuating antitumor and enhancing immunity.

The product of Invention I is distinct from the methods of Inventions III-X because the product of Invention I can be neither made by nor used in the methods of Inventions III-X.

The method of Invention III and the product of Invention II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the lectin can be isolated using lectin affinity chromatography and ion exchange chromatography.

The product of Invention II and the methods of Invention IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Invention IV and V are alternative processes of use of the product of Invention II.

The product of Invention II is distinct from the methods of Invention VI-X because the product of Invention II can be neither made by nor used in the methods of Inventions VI-X.

The product of Invention VII and the methods of Invention VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Invention VI and VIII are alternative processes of use of the product of Invention VII.

The product of Invention VII is distinct from the methods of Invention III, IV, V, IX and X because the product of Invention VII can be neither made by nor used in the methods of Inventions III, IV, V, IX and X.

The product of Invention IX and the method of Invention X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the lectin isolated from Korean Mistletoe can be used in the method of Invention X.

The product of Invention IX is distinct from the methods of Invention III-VIII because the product of Invention IX can be neither made by nor used in the methods of Inventions III-VIII.

The methods of Invention III-X are distinct from each other because the method steps and outcomes are wholly different among Inventions III-X, therefore Inventions III-X are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-X require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation of Examiner Hope Robinson with Sheldon McGee on May 10, 2002, a provisional election was made with traverse to prosecute the invention of Group V, claims 29-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-28 and 35-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Sequence Listing

4. A paper copy of sequence listing filed March 4, 2003 is acknowledged, and CRF has been entered. During a telephone conversation with Sheldon McGee on March 4, 2003, applicant indicates SEQ ID NOs:15 and 16 are related to KML-IIU, and SEQ ID NOs:13 and 14 are related to KML-IIL.

Objections

The disclosure is objected to because of the following informalities:

5. The specification indicates Fig. 33 and Fig. 34 show the nucleotide sequence and the amino acid sequence of KML-IIU and KML-IIL, respectively (pages 7, 8 and 49), however, Figs 33 and 34 have not been provided. Appropriate correction is required.

6. Tables 9a, 9b, 9c and 9d show amino acid sequence comparison of Korean Mistletoe lectins, European Mistletoe lectins and other related lectins. However, the numbering of amino acid residues is not provided in the sequence comparison (especially in the A chain), it is not clear where is the sequence homology among various sequences. The specification does not define GI in Table 9a. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-34 are indefinite because the claims lack essential steps in the method of effectuating antitumor activity in animals. The omitted steps are the effective amount of lectin from Korean misletoe administered and the outcome for the treatment. Claims 30-34 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 29, 30, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon *et al.* (International J. Immunopharmacology 20, 163-172 (April-May 1998)).

Yoon *et al.* teach an aqueous extract (KM-110) prepared from Viscum album coloratum (Korean mistletoe) inhibits tumor metasis in experimental lung metastatsis of B16-BL6 melanoma or colon 26-M3.1 carcinoma cells (Table 1), and spleen metastasis of L5178Y-ML25 lymphoma cells (Table 2) when administered of KM-110 (100 μg) before tumor inoculation

(pages 166-167; claims 29, 30, 31 and 33). Claims 29, 30, 31 and 33 are anticipated by the reference because the extract of KM-110 containing isolated lectins as shown in the specification has antitumor activity, and claims 30, 31 and 33 recite the lectin of KML-IIU and/or KML-IIL, but, no characteristic or property of the protein is indicated, thus any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 29, 30, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khwaja *et al.* (Proc. Am. Assoc. Cancer Res. Annu. Meet. 28, 303 (1987)) taken with Khwaja (U. S. Patent 5,565,200).

Khwaja *et al.* teach a lectin, which is isolated from the aqueous extract of Viscum album, Coloratum (Korean mistletoe) by precipitation with 70% ammonium sulfate, absorbing on

Sepharose 4B column, and eluting with 0.15 M lactose in 0.5 M NaCl, has antiocancer activity against the growth of leukemia L1210 cells in culture with IC_{50} of 0.66 ng/ml, and the SDS gel electrophoresis of lectin shows two major bands 29 and 36 kDa (whole abstract; claims 29, 30, 31 and 33). However, Khwaja *et al.* do not dislose the administration of the lectin from Korean mistletoe to an animal. Khwaja teaches aqueous extracts from Korean mistletoe, which contain lectins, viscotoxins and alkaloidal compounds, exhibit antileukemia activity against L1210 cells and anticancer activity in animals bearing tumor cells (column 11, line 57-column 12, line 35; Example 1; claim 12 of the 200' patent). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to use the isolated lectin taught by Khwaja *et al.* in treating an animal having cancer because the use of an active ingredient in the extract would provide an alternative method for effective treatment of cancer. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made. Claims 30, 31 and 33 recite the lectin of KML-IIU and/or KML-IIL, but, no characteristic or property of the protein is indicated, thus any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

March 30, 2003

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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